REMARKS

Applicants had filed a Petition Under 37 C.F.R. § 1.181 And M.P.E.P. §§ 1003 ¶6 And 2307.02 on April 7, 2006 ("Petition"). As Exhibit D to the Petition, Applicants had provided an Amendment under 37 C.F.R. § 1.116. In an Advisory Action dated April 25, 2006, Applicants were informed that the Amendment of April 7, 2006 would not be entered. Applicants submit herewith a Request for Continued Examination and a further Amendment and respectfully request that the currently filed Amendment be entered.

According to the final Office Action dated January 4, 2006, claims 7-10, 12-18, and 20-22 are pending and claims 9, and 13 to 16 are withdrawn from consideration. Claim 7 has been amended to more clearly point out and claim what Applicants consider as their invention. Support for the amendment to claim 7 can be found in the specification of the application as filed, *e.g.*, at p. 27, *ll.* 31-35. Support for the amendment to claim 7 can also be found in the earliest priority application, which issued as U.S. Patent No. 5,840,520 (the "'520 Patent"), *see, e.g.*, at col. 42, *ll.* 55-59, which describes the rescue of "stable and infectious RSVs, as noted in Section 5." This section of the specification, for clarity of discussion, describes the invention in terms of rescuing influenza virus, but analogously applies the principles to RSV (see col. 14, *ll.* 46-54), and in particular, at col. 22, *ll.* 22-24 states: "[t]hese altered viruses would then be growth competent and would not need helper functions to replicate."

No new matter has been introduced, and claims 7-10, 12-18, and 20-22 are pending upon entry of the present amendment.

The rejections under 35 USC § 112, first paragraph, were addressed in the Amendment under 37 C.F.R. § 1.111, filed June 28, 2005, the Supplemental Response, filed October 4, 2005, and the Declaration of Richard R. Spaete under 37 C.F.R. § 1.132 (the "Spaete Declaration"), filed October 4, 2005. Although requested by Applicants, the Examiner did not refute the facts set forth in the Spaete Declaration by providing an affidavit pursuant to the provisions of 37 C.F.R. § 1.104(d)(2).

THE REJECTIONS UNDER 35 USC § 102(b) SHOULD BE WITHDRAWN

Claim 7 is rejected under 35 U.S.C. § 102(b) over Calain and Roux, 1993, J. Virology 67(8):4822-4830 ("Calain"). In particular, it is argued that Calain discloses a recombinant Sendai virus comprising an insertion of six nucleotides. Applicants respectfully request that the rejection over Calain be withdrawn in view of the present clarification of the claim language.

THE LEGAL STANDARD

Anticipation requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee. *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F. 3d 299, 302 (Fed. Cir. 1995). An anticipating reference must describe and enable the claimed invention, including all the claim limitations, with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention. *In re Spada*, 911 F.2d 705 (Fed. Cir. 1990); *Crown Operations International, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002).

The standard for an anticipatory reference is set forth in *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987): "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *See also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989)(holding that "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim"). Further, the anticipating reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter. *PPG Industries, Inc. v. Guardian Industries Corp.* 75 F. 3d 1558 (Fed. Cir. 1996).

CALAIN DOES NOT TEACH EVERY CLAIM ELEMENT

Calain describes the replication and encapsidation of a defective interfering RNAs in the presence of the Sendai virus wild type RNA polymerase. Calain further describes genetic manipulation of these defective interfering RNAs. However, Calain does <u>not</u> disclose an

infectious, replication competent, viral particle wherein the genetically manipulated viral particle is replicated in the absence of helper function. Rather, the defective interfering RNAs described in Calain are subgenomes or deleted genomes (Calain *et al.*, 1992, Virology 191:62-71; see Exhibit 1 to the Amendment of April 7, 2006). In fact, the defective interfering RNA used in Calain is 1,410 nucleotides long (Calain, at p. 4823, left col., *ll.* 2-3), and thus cannot possibly encode all the genes required for viral replication and infection; the L gene alone is over 6 kb long (Shioda *et al.*, 1986, Nucleic Acid Res. 14:1545-1563; attached as Exhibit 2 to the Amendment of April 7, 2006). Thus, although the defective interfering RNA in Calain is genetically manipulated, the resulting derivative can only be replicated in the presence of helper functions, such as providing the N, P, and L-genes *in trans (see, e.g.*, Figure 5a of Calain).

In contrast, claim 7 as amended now makes it clear that the claimed viruses are replication competent even in the absence of any helper functions, such as providing N, P, and L genes *in trans*. The genetically modified virus particles of the present invention are initially generated by cotransfection of a cDNA encoding the virus and plasmids encoding the N, P, and L genes into a host cell (see, *e.g.*, Section 7, beginning at p. 45 of the present application; see also Section 9, beginning at col. 42 of the '520 Patent). The resulting rescued virus is replication competent in the absence of helper function. See, *e.g.*, Section 7, beginning at p. 45 of the present application. This section shows that the rescued virus was capable of further replication without helper functions as demonstrated by the formation of plaques when host cells where infected with the rescued virus (p. 47, *ll.* 12-32).

Thus, Calain does not teach all claim elements of claim 7. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 7 over Calain under 35 U.S.C. § 102(b) should be withdrawn.

Conclusion

Applicants respectfully request that the present remarks and amendments be entered and made of record in the instant application. The Examiner is invited to call the undersigned with any questions or concerns regarding the above.

No fee is believed to be required for this response. However, should any fee be due, please charge the required amount to Jones Day Deposit Account No. 503013.

Respectfully submitted,

Date June 30, 2006

30,742
(Reg. No.)

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